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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,528	09/22/2003	Rikako Kono	0283-0177P	5919

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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER

AULAKH, CHARANJIT

ART UNIT PAPER NUMBER

1625

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,528

Applicant(s)

KONO ET AL.

Examiner

Charanjit S. Aulakh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. According to paper filed on April 19, 2004, the applicants have amended claims 1-5 and furthermore, have elected group III for further prosecution in response to restriction requirement.

Response to Arguments

2. Applicant's arguments filed on April 19, 2004 have been fully considered but they are not persuasive regarding restriction requirement. The examiner does not agree with the applicants arguments that there is no serious burden in searching all the groups. First of all, original claims were directed to compounds and these compounds of different inventions were classified in different classes and subclasses. The applicants have now amended claims to method claims. Although amended claims are classified in class 514 yet based on the values of variables A and Q, these different inventions will be classified in numerous (more than 40) subclasses and therefore, does constitute a burdensome search. However, upon applicant's request, group I has now been included with the elected group III for further examination. Thus, restriction requirement as indicated is proper and thereby made final.

3. Claims 1-5 are pending in the application.

Priority

4. The priority claim based on the provisional application 60/411, 749 filed on Sep. 19, 2002 is not granted since the instant application was filed (Sep. 22, 2003) more than a year after the filing date of the provisional application. Therefore, the earliest priority date is now march 13, 2003 based on the foreign application.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The following eight different factors (see *Ex parte Foreman*, 230 USPQ at 547; *Wands*, *In re*, 858 F. 2d 731, USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed :

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art and the breadth of claims.

The instant compounds are shown to relax potassium-induced contraction of isolated rabbit urinary bladder in vitro and substance P-induced bladder contractions in vivo.

However, there is no teaching either in the specification or prior art reference showing how to study the effects of any compounds for opening a large conductance calcium-

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activated K channel following their in vivo administration and furthermore, where are these channels located in the mammal? There are no working examples present or guidance provided for assessing the activity of instant compounds for opening these channels in any specific tissue following their administration in vivo. The instant compounds of formula (I) encompasses thousands of compounds based on the variables R1-R6, ring A and ring Q and therefore, in absence of such teachings, guidance or presence of working examples, it would require undue experimentation to demonstrate the effectiveness of the instant compounds for opening these channels following their in vivo administration.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claim 1, it is not clear where the calcium-activated K channels are opened in the mammal and furthermore, what happens after their opening? The applicants are suggested to include the specific utility such as treating specific disease in the claim since claims directed to mechanism are not a patentable subject matter. Claims 2-4 recite the limitation "the opener" in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 1-5 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Leonardi (U.S. Patent no. 6,440,963, cited on applicants form 1449).

Leonardi discloses use of selective COX-2 inhibitors for the treatment of urinary incontinence. The method of treating urinary incontinence using compounds B, D and E (see column 16) disclosed by Leonardi clearly anticipate the instant claims. It is of note that mechanism is not critical since it will be inherent to open calcium-activated K channels since these compounds have pharmacological utility following their in vivo administration.

10. Claims 1-5 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Hongu (WO 02/083111).

Hongu discloses large conductance calcium-activated K channel opener. The method of opening large conductance calcium-activated K channel using compounds 29, 30, 59, 61, 87 and 88 (see pages 39, 40, 47, 48 and 60, respectively as well as claims 1-7) disclosed by Hongu clearly anticipate the instant claims.

11. Claims 1-5 are objected as containing non-elected subject matter.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charanjit S. Aulakh
Primary Examiner
Art Unit 1625